

FEB 26 2004

K03/097

10. SMDA Summary of Safety and Effectiveness SMDA Summary of Safety and Effectiveness

510(k) Summary

Polaris® Pressure Adjustable Valve

A. Submitter Information

Sponsor:

SOPHYSA SA
C/o Interactive Consulting Inc.
70 Walnut Street
Wellesley, MA 02481
Tel: (781) 239-8108
Fax: (781) 863-6497

Manufacturer:

SOPHYSA SA
22 rue Jean Rostand
Parc Club Orsay Université
91893 ORSAY Cedex, France
Tel: 011-331-69 35 35 00
Fax: 011 331 69 35 36 90
Website : www.sophysa.com

Contact Person: Jean-Christophe Audras, Regulatory Affairs
Date Prepared: April 4, 2003

B. Device Identification

Common/Usual Name: Hydrocephalus Shunt
Proprietary Name: Polaris® Pressure Adjustable Valve System
Regulatory Class: Class II by 21 CFR 882.5550

C. Identification of Predicate Device(s)

The Polaris® Pressure Adjustable Valve is substantially equivalent to the SOPHYSA Sophy® SM8 Valve (K013488) previously cleared and currently marketed.

D. Device Description

The Polaris® Pressure Adjustable Valve is an implantable device designed for the treatment of hydrocephalus in adult and pediatric patients by shunting, thereby providing continuous, controlled intraventricular pressure and CSF drainage from the cerebral ventricles. Intraventricular pressure is maintained at a constant level by the device's ball-in-cone valve seat design, and the value is pressure-adjustable transcutaneously. Drainage is directed to the abdominal cavity or to the right atrium of the heart. The basic settings of the Polaris® Valve are 30, 70, 110, 150 and 200. Adjustments to intermediate pressures are made manually in 40 mm H₂O increments (decrements) in three operating ranges, low pressure (LP = 30 mm H₂O), medium pressure (MP = 110 mm H₂O), and high pressure (HP = 200 mm H₂O).

The specific feature of the self-locking rotor-shuttle micro-magnet system of the passive Polaris® SPV Valve is that the adjustment position of each pressure setting cannot be changed by a unidirectional magnetic field. A domestic magnetic field or an exposure to MRI attracts the shuttles in the same direction and thus cannot unlock them simultaneously, therefore the rotor cannot be mobilized.

E. Substantial Equivalence

The Polaris® Pressure Adjustable Valve is substantially equivalent to the Sophy® Pressure Adjustable Valve System SM8 (K013488) in terms of intended use, materials, biocompatibility, design, performance, function, and operating characteristics.

F. Indications for Use

To drain cerebrospinal fluid (CSF) for the management of hydrocephalus.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2004

Sophysa SA
c/o Ms. Jacqueline E. Masse
Interactive Consulting
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K031097

Trade/Device Name: Polaris Pressure Adjustable Valve SPV, SPVA, SPVB
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: November 25, 2003
Received: November 28, 2003

Dear Ms. Masse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

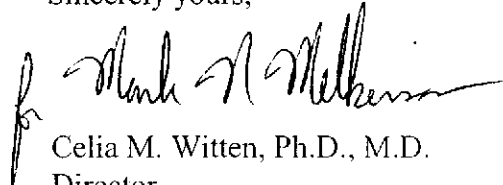
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031097

Device Name: Polaris Pressure Adjustable Valve SPV, SPVA, SPVB

Indications For Use:

To drain cerebrospinal fluid (CSF) for the management of hydrocephalus

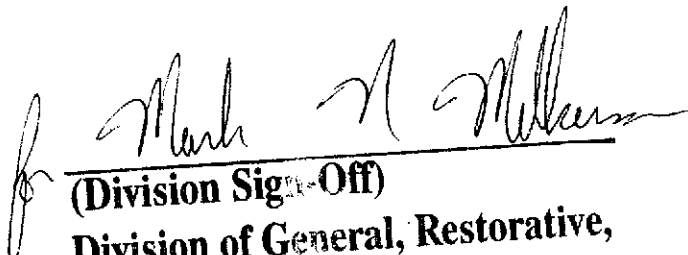
Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number: K031097